REMARKS

The non-statutory double patenting rejections are noted. Applicants will file Terminal Disclaimers upon indication that the claims are otherwise allowable. The indicated allowability of claims 13-16 and 18-20 is noted with thanks.

The claims have been amended to clarify that the pharmaceutical ingredients consist of powdered pharmaceutical ingredients, and that the ingestible membrane has a selected permeability porosity to fluids for controlled release of the powdered pharmaceutical ingredients. No new matter has been entered by any of the foregoing amendments.

Turning to the art rejections, the Examiner's rejection of claims 1, 4 and 9-12 as being anticipated under 35 U.S.C. § 102 from Depui et al. (WO 97/25065) is in error. The Examiner posits at page 8 of the Action that Applicants rely on features that are not in the rejected claims. Claim 1, as amended, requires, in part, that the pharmaceutical ingredients consist of powdered pharmaceutical ingredients, and that the delivery system includes an ingestible membrane having selected permeability porosity to fluids at a selected site or sites within a patient's alimentary canal. This claim therefore (1) precludes enteric coated active ingredients; (2) requires pharmaceutical delivery at specific sites; and, (3) relies on porosity of the membrane to control the release of pharmaceutical agents. As recognized by the Examiner, Depui et al. does not teach this. Thus, Applicants' claim 1, and the several claims dependent thereon cannot be said to be anticipated, or for that matter obvious from Depui et al.

The rejection of claims 1, 4, 9-12, 17 and 21 as obvious under 35 U.S.C. § 103(a) from Depui et al. and Sanso (US 6,350,468) likewise is in error. The deficiencies of Depui et al. vis-à-vis claim 1 are discussed above. It is not seen that Sanso supplies the missing teachings

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to Depui et al. to achieve or render obvious claim 1 or any of the claims which depend thereon. Sanso teaches a double capsule consisting of an external capsule and an internal capsule, with both capsules containing one or more pharmaceutical agents. Applicants' independent claim 1, as amended, requires that the two or more different powdered pharmaceutical ingredients are combined in and separated from one another on an ingestible membrane which forms a single delivery package. Sanso does not teach this. Rather, Sanso teaches the combination of pharmaceutical ingredients within a double capsule system. Thus, in Sanso, in order for the drugs contained in the inner capsule to be released, the external capsule shell must already be dissolved. And, Sanso does not teach a method for delivering the pharmaceutical agents to selective sites. Sanso also does not teach either capsule having a porous membrane to achieve controlled release of the pharmaceutical agents from either capsule. Thus, no combination of neither Depui et al. and Sanso would achieve or render obvious claim 1 or the several claims dependent thereon.

The Examiner's rejection of claims 1, 3-9, 11 and 12 as obvious under 35 U.S.C. § 103(a) from Sturzenegger et al. (US 4,197,289) likewise is in error. Sturzenegger et al.'s contribution to the art is to provide an oral dosage pharmaceutical free of conventional adjunct materials. Sturzenegger et al. accomplishes this by depositing a pharmaceutical ingredient or ingredients onto a web, and layering and sealing the layers to completely internalize the pharmaceutical ingredient(s). Sturzenegger et al. does not teach fixed unit dose quantities of multiple pharmaceutical ingredients separated from one another on a porous ingestible membrane having a selected permeability porosity to fluids at a selected site or sites within a

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patient's alimentary canal as required by claim 1. Accordingly, neither claim 1, nor any of the claims dependent thereon can be said to be achieved or obvious from Sturzenegger et al.

The rejection of claims 1, 3-10 and 12 as obvious under 35 U.S.C. § 103(a) from Sturzenegger et al. in view of Digenis et al. (US 5,672,359) also is in error. The deficiencies of Sturzenegger et al. with regard to claim 1 are discussed above. Digenis et al. does not supply the missing teachings to Sturzenegger et al. to achieve or render obvious claim 1 or any of the claims dependent thereon. Digenis et al. teaches a three compartment capsule including an outer layer incorporating a drug on the outer part of the capsule 12; an intermediate compartment 11 containing a drug; and an inner compartment containing small pellets 14 of a drug. In Digenis et al., the outer layer provides essentially immediate release of the drug. Applicants' claimed invention, on the other hand, requires controlled release of multiple pharmaceutical agents depending on the site in the alimentary canal where the delivery package is located. Since Sturzenegger et al. fails to teach a pharmaceutical delivery package formed in part of an ingestible membrane having a selective permeability porosity to fluids at a selected site or sites within a patient's alimentary canal as required by Applicants' claim 1, and Digenis et al. also fails to include this teaching, no combination of Sturzenegger et al. and Digenis et al. reasonably could be said to achieve or render obvious claim 1 or the several claims dependent thereon.

Turning to the rejection of claims 1, 3-10 and 12 as obvious under 35 U.S.C. § 103(a) from Sturzenegger et al. in view of Depui et al., the deficiencies of Depui et al. and Sturenegger et al. have been discussed above. Moreover, Depui et al. and Sturzenegger are very different in their teachings, and have little in common other than the fact that both relate to pharmaceutical

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delivery systems. Depui et al. is a capsule or tablet, while Sturzenegger et al.'s contribution to the art is a pharmaceutical delivery package formed on an edible web as an alternative to conventional solid oral dosage forms of pharmaceuticals, i.e., tablets and capsules, which Sturzenegger et al. teaches as being "disadvantageous." (See column 10, lines 11-55). Thus, one skilled in the art would not be motivated to combine the references. And, no combination of Depui et al. and Sturzenegger et al. reasonably could be said to achieve or render obvious claim 1 or the several claims dependent thereon, in any event.

Having dealt with all the objections raised by the Examiner, the Application is believed to be in order for allowance. Early and favorable action is respectfully requested.

In the event there are any fee deficiencies or additional fees are payable, please charge them (or credit any overpayment) to our Deposit Account Number 08-1391.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on January 5, 2006, at Tucson, Arizona.

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